7. UNCERTAINTIES

The ultimate goal of a health risk assessment is to provide scientific, objective, and balanced risk estimates that enable effective risk management. Of equal importance is the calculation of the risk values and the discussion of the methods employed in developing those values. In this section, risk values are evaluated to identify the type and degree of uncertainty introduced in any risk assessment process.

When using the health risk assessment results for remedial decision making, one should consider the processes employed in deriving the predicted risk values. Decision-makers, as well as the general public, can be misled if they rely only on a simplified numerical presentation without considering uncertainties, limitations, and assumptions inherent in the health risk assessment process. For example, the small impact of a 1×10^{-6} lifetime risk of cancer may be calculated for an individual from exposure to a particular source of contamination. However, if the uncertainty in this number is measured in orders of magnitude, then the real risk from this source may in fact be higher than the risk from another contaminated source that has a calculated risk of 1×10^{-5} but a small degree of uncertainty. Alternatively, an upper-bound lifetime risk of 1.5×10^{-4} may be calculated and appear to represent an unacceptable risk. However, the actual risk may be 1, 2, or even 3 orders of magnitude smaller.

The uncertainties and conservatism inherent in this risk assessment are considered in this section, to provide the reader with a proper perspective of the overall quality of the predicted risk values. The discussion follows the same flow process used to calculate the risk values.

7.1 SOURCES OF UNCERTAINTY

Although there are potentially many sources of uncertainty introduced while deriving estimated risks, health risk assessments generally carry two types of uncertainty, measurement and

informational. Measurement uncertainty refers to the usual variance that accompanies scientific measurements (such as the range of an exposure estimate) and reflects the accumulated variances of the individually measured values. Examples of this type of uncertainty include the use of discrete samples to define overall site conditions, and the variations in sample results of constituents of potential concern (COPCs).

A different kind of uncertainty arises if information needed to complete the risk calculations is unavailable. In some instances the impact is significant, such as the absence of information on the effects of human exposure to a constituent or on the biological mechanisms of action of a constituent (EPA 1992b, 1992d). In other instances, the overall impact can be minimized using the information available, coupled with reasonable assumptions to place an upper limit on the uncertainty. This latter approach can be applied to such uncertainties as the interactions of constituent mixtures in the human body, the use of computer model default values for site conditions, the accuracy with which the model itself represents actual environmental or biological processes, the manner in which the exposure scenario is developed, and the high-to-low dose and inter-species extrapolations for dose-response relationships.

The production of a risk assessment is an iterative process involving sequential evaluation of all site data. Once any type of uncertainty is introduced into the early stages of the process, it will propagate as calculations proceed. In its guidance for human health risk assessments, the EPA states that "it is more important to identify the key site-related variables and assumptions that contribute most to the uncertainty than to precisely quantify the degree of uncertainty in the health risk assessment" (EPA 1989a).

7.2 Uncertainties in Selection of Constituents of Potential Concern

The selection of which constituents to evaluate is a potential source of uncertainty in any health risk assessment. Specific uncertainties related to COPC determination are presented below.

7.2.1 Species of Site Constituents

A major concern in any risk assessment is the reliability of COPC identification to ensure that all site constituents have been identified and that all identified constituents originated from the site. The quality of COPC identification data is directly related to the quality of the site contamination data. This is controlled in the design of the sampling and analysis plan, which details both the sampling and analytical protocols.

The proper identification of COPCs in this risk assessment has been confirmed by a review of the large volume of data collected to characterize soil constituents. Process and operational records of the C-6 facility have also been used to confirm the field data and identify possible site constituents. Because the COPCs investigated in this risk assessment include all major constituents detected at the site, it is highly unlikely that aggregate risks presented by these COPCs would be significantly underestimated.

7.2.2 Sampling Design

Uncertainty is inherent in soil sampling data due to the heterogeneity of the waste forms and concentrations as well as the bias introduced in the sampling program. The soil sampling programs implemented at Parcel A do not necessarily represent a random sampling. In fact, the programs purposely focused on areas exhibiting the greatest contamination in previous studies, to ensure detection of any significant concentrations of constituents. Selecting sampling locations in this way led to a conservative bias for many constituents and an upper-bound estimate of Parcel A constituents.

7.2.3 Data Quality

In validating and determining data usability for the risk assessment, it became evident that not all site data were obtained through the same sampling plans. Since 1987, there have been at least three major sampling programs executed by three different companies. The field and analytical

protocols differed between stages. Inconsistency in these operations has resulted in data with unequal quality, therefore introducing uncertainty into the final risk values.

It is unlikely that this inconsistency is a major contributor to the overall uncertainty. Some of the early, low-quality data either do not represent the current site conditions or fail to meet the risk assessment data quality objectives and were not included in the risk calculations.

7.2.4 Detection Limits

A major source of uncertainty related to the extent of contamination is the treatment of "nondetect" analytical results. In selecting COPCs, it was assumed that nondetect analytical results were equal to the detection limit divided by the square root of 2, and that the constituent is distributed lognormally in the medium. This approach is conservative and ensures that nondetect analytical results do not artificially underestimate potential constituent concentrations.

7.3 Uncertainties in Exposure Assessment

The uncertainty of exposure point concentrations estimated in this risk assessment depends on the quality of the selected input parameters (diffusion coefficients, groundwater flow, air flow, etc.), computer model characteristics, release mechanisms, and source terms. This section addresses the uncertainty related to the quantification of exposure concentrations and COPC intakes.

7.3.1 Site Setting

As presented in Section 4, many attributes of the site setting influence the outcome of exposure predictions. One of the key sources of uncertainty associated with predicting exposures at a site is the disposition of the property itself. However, the site setting at Parcel A has been solidified through proposed deed restrictions, which significantly minimize the uncertainty associated with projecting potential future exposures.

7.3.2 Receptor Selection

The Parcel A land use and exposure scenarios (Section 4), including the associated receptor-specific exposure parameters (Section 6, Table 6-1), each represent RME conditions. Therefore, the combination of these conservative exposure assumptions guarantees the health and safety of those who will inhabit adjacent properties or visit Parcel A.

7.3.3 Exposure Parameters

Each exposure parameter value selected for use in this risk assessment (Section 6, Table 6-1) also has uncertainty associated with it. Many exposure parameters published in EPA risk assessment guidance documents are based on surveys of physiological and lifestyle profiles across the United States. The attributes and activities studied in these surveys generally have a broad distribution. To account for this distribution, the exposure parameters used in this risk assessment generally represent the habits defined by the 90-to-95-percent upper confidence limits (UCLs) for the entire population. The effect of the conservative nature of these parameters on the intake and risk modeling is linear to the final predicted risk values.

As an example of an overly conservative exposure assumption, receptors were assumed to inhale air at the location of highest predicted annual average concentration for 8 hours per day, 250 days per year for 25 years. It is unlikely an actual commercial/industrial worker would be exposed in this manner.

Moreover, the construction worker was assumed to be exposed to COPCs in all media via applicable exposure pathways simultaneously. The occurrence of multiple exposure routes and COPCs in multiple media on a receptor at a location may not correspond to reality. Such combination of exposure routes is believed to result in increased conservatism.

7.3.4 Use of the 95 Percent Upper Confidence Limit

One key source of conservatism built-in to this risk assessment is the use of the 95 percent UCL in estimating COPC levels and exposure concentrations. Statistically, this means that 95 percent of the time, the actual mean concentration is less than the value used in the exposure assessment. Conversely, 5 percent of the time the actual mean concentration is greater than the value used in the exposure assessment.

Because the constituents are discrete and localized, the UCL for lognormally distributed environmental data was used to estimate the level of Parcel A concentrations. A lognormal distribution indicates that with regularly spaced samples, there will be many samples with low levels of constituents and very few with high levels. The use of the 95 percent UCL in assessing soil concentrations at Parcel A (including uncontaminated areas) has resulted in upper-bound estimates of COPCs and exposure concentrations.

7.3.5 Algorithms for Computer Codes

There is additional built-in conservatism in the computer models used to predict exposure concentrations. Due to the complexity of the natural environment, programmers have used simplifying but conservative assumptions in developing the computer codes. Each assumption carries with it a level of uncertainty. In addition, most model parameter values use maximized estimates of transport. Thus, the modeled concentrations are generally higher than the measured concentrations in the field.

7.3.6 Input Parameters

In computer modeling, if site-specific data are unavailable, necessary assumptions are made either using regulatory default values or conservative professional judgment based upon literature. All of these efforts are designed to overestimate exposure to ensure that some extreme and highly unlikely exposure conditions are covered by the predicted risk values. For instance, in

air dispersion modeling, the receptor is assumed to be continuously exposed to the maximum annual on-site and off-site COPC concentrations during the entire exposure period investigated.

7.4 UNCERTAINTIES IN TOXICITY ASSESSMENT

Considerable uncertainty is associated with the qualitative (hazard assessment) and quantitative (dose-response) evaluations of constituent toxicity. The hazard assessment deals with characterizing the nature and strength of the evidence of causation, or the likelihood that a constituent that induces adverse effects in animals will induce adverse effects in humans. Dose-response assessment is the process of characterizing the relationship between the administered dose of an agent and the incidence and severity of adverse health effects in an exposed population.

Regulatory agencies consistently use significant safety factors in determining the toxicity of a constituent to a human receptor, to ensure that potential health impacts to the exposed receptors will not be underestimated. In this report, the toxicological constants of COPCs arise out of the application of guidelines recommended by the agencies involved and are not self-generated. Consequently, the built-in uncertainty in determining the toxicity of a constituent is carried through to the predicted risk values.

When determining the appropriate values for toxicity parameters, it is usually necessary to extrapolate experimental toxicity data to humans under specified conditions. These extrapolations involve many assumptions and have a certain amount of inherent uncertainty. In the absence of (or in addition to) reliable epidemiological data, experimental toxicity data are used for dose-response assessments. The inference that adverse effects found in animal bioassays are indicative of likely human toxicity is fundamental to toxicological research and risk assessment. This premise has been extended from experimental biology and medicine into the experimental observation of carcinogenic effects.

Extrapolation from animals to humans is also inherent in the process of toxicity testing, as is route-to-route extrapolation. Both of these extrapolations are examples of the limitations of toxicity data. The associated uncertainty of these two issues is discussed in greater detail below.

7.4.1 Extrapolation

Uncertainties related to toxicity assessment are inherent in the modeling of dose-response relationships for exposure to constituents and in calculating numerical estimators used to predict health effects with a margin of safety. Examples of inherent uncertainties in numerical estimators include factors incorporated into reference dose (RfD) values and cancer slope factors to provide a margin of safety for use in human health assessments. Examples of uncertainties inherent to modeling of dose-response relationships, upon which RfD values and/or cancer slope factors were based, include:

- Extrapolation of findings in animal experiments to humans (uncertainties arising from surface-area-based dose conversion and interspecies extrapolation)
- Extrapolation of findings at high exposure levels to low exposure levels
- Extrapolation of findings from acute exposures to chronic exposures and/or occupational conditions to nonoccupational or environmental conditions.
- Extrapolation of findings for oral toxicity values to dermal toxicity values.

The level of uncertainty for different constituents varies because information concerning some constituents and their associated health effects is comparatively scarce, while for others more information is available from health effects studies.

There is also uncertainty regarding the carcinogenicity of the COPCs. For example, TCE is considered to be a probable carcinogen; however, epidemiological evidence of TCE-induced excess cancer risk is very difficult to obtain. This is largely because currently available studies of humans lack quantitative information concerning TCE exposure, previous TCE exposures, and

profiles of receptors' lifestyles (such as smoking). These facts weaken the potential to discern the carcinogenicity of TCE in humans.

7.4.2 Additive Effect of Constituent Mixtures

For noncarcinogenic constituents, the use of the hazard index (HI) has introduced uncertainty and a measure of conservatism to the estimate of risk. The basis for using the HI is the assumption that the toxic effects of all noncarcinogenic constituents are additive. Additive toxicity assumes that constituents act in a concerted fashion to generate toxicity. It is clear, however, that the noncarcinogenic COPCs at Parcel A do not all have identical toxic effects and mechanisms of action. Hazard quotients (HQs) have not been calculated for each generalized toxic effect or mechanism of action as recommended in the Risk Assessment Guidance for Superfund (RAGS, EPA 1989a). If the HI calculated in Section 5 were segregated according to target organ, the overall potential for noncarcinogenic effects would be further diminished.